DIAZYME

DEC 7 2005

K051714

Summary

Submitter's name: Diazyme Laboratories Division, General Atomics

Submitter's address: 3550 General Atomics Court
San Diego, CA 92121

Phone: 858-455-4754
Fax: 858-455-4750

Name of Contact Person: Huan Tran
Diazyme Laboratories Division
General Atomics
3550 General Atomics Court
San Diego, CA 92121
Phone: 858-455-4761
Fax: 858-455-4750

Date the summary was prepared: June 17, 2005

Name of the device: Total Bile Acids Assay
Trade Name: Total Bile Acids Assay
Common/Usual Name: Enzymatic Assay, TBA
Classification Name: Radioimmunoassay, Cholyglycine, Bile acids
Device Class: II

Predicate Device:

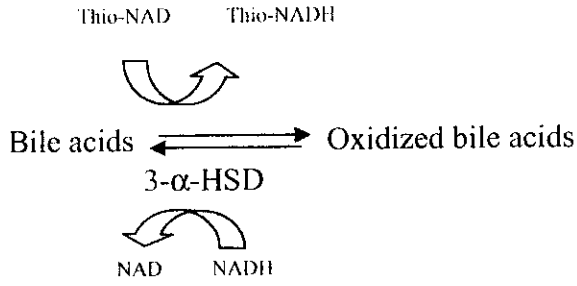
The legally marketed device to which we are claiming equivalence [807.92(a)(3)]: Bile Acids Reagent (K872296) manufactured by Trinity Biotech, USA, 1930 Innerbelt Business Center Drive, St. Louis, MO, 63114.

Description of the device

The Diazyme's Total Bile Acids assay is a clinical test kit, intended for quantitative determination of total bile acids in serum by an enzymatic method.

The Diazyme's Total Bile Acids assay is comprised of Reagent 1, Reagent 2, and a calibrator.

The reagents of the assay kit are stable liquid formulation that allows ease of use coupled with enhanced performance characteristics. In the presence of Thio-NAD, the enzyme 3-α–hydroxysteroid dehydrogenase (3-α–HSD) converts bile acids to 3-keto steroids and Thio-NADH. The reaction is reversible and 3-α-HSD can convert 3-keto steroids and Thio-NADH to bile acids and Thio-NAD. In the presence of excess NADH, the enzyme cycling occurs efficiently and the rate of formation of Thio-NADH is determined by measuring specific change of absorbance at 405nm.



Intended Use of the Device:

Total Bile Acids Assay is intended for the *in vitro* quantitative determination of total bile acids(TBA) in human serum samples.

Total Bile Acids Assay contains a bile acid calibrator. The calibrator is design to be used with the assay for the quantitative determination of TBA in serum.

Total Bile Acids Assay has control design to be used with the assay for the quantitative determination of TBA in serum.

Performance Characteristics

Diazyme's Total Bile Acids Assay is a two reagents based kinetic assay system. The assay offers excellent precision as shown in the table below:

	8 μM	23 μM
Intra-Assay Precision	CV%= 3.9%	CV%= 1.3%
Inter-Assay Precision	CV%= 2.9%	CV%= 2.6%

Diazyme's Total Bile Acids Assay has a good correlation with Trinity's method with a correlation coefficient of 0.99. We have conducted interference study by spiking the substances to be tested to the pooled human sera and found less than 1% interference at the indicated concentrations:

Interference	Concentration
Triglyceride	750 mg/dl
Bilirubin	50 mg/dl
Ascorbic Acid	50 mg/dl
Hemoglobin	500 mg/dl

Conclusion: Comparison analysis presented in the 510K submission for this device in the comparison section, together with linearity, precision and interference study presented demonstrated that the Diazyme's Total Bile Acids Assay has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme's Total Bile Acids Assay and legally marketed predicate when testing clinical patient samples. Therefore, Diazyme's Total Bile Acids Assay is substantially similar to the commercially available products to measure bile acids in human serum samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 7 2005

Mr. Huan Tran
Quality Assurance Manager
Diazyme Laboratories Division
General Atomics
3550 General Atomics Court
San Diego, CA 92121

Re: k051714
Trade/Device Name: Total Bile Acids Assay
Regulation Number: 21 CFR 862.1177
Regulation Name: Cholylglycine test system
Regulatory Class: Class II
Product Code: KWW, JJX
Dated: November 18, 2005
Received: November 18, 2005

Dear Mr. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: k051714

Device Name: Total Bile Acids Assay

Indications For Use:

Total Bile Acids Assay is intended for the *in vitro* quantitative determination of total bile acids (TBA) in human serum samples. Total bile acids are metabolized in the liver and serve as a marker for normal and abnormal liver function. Serum total bile acids are increased in patients with liver disease.

Total Bile Acids Assay contains a bile acid calibrator. The calibrator is design to be used with the assay for the quantitative determination of TBA in serum.

Total Bile Acids Assay has control design to be used with the assay for the quantitative determination of TBA in serum.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051714